WARNING LETTER

March 26, 2003

Mr. Guillermo Herrera C., President
Exportadora P.M.T., S.A.
P.O. Box 306-1250
San Jose, Costa Rica 6155

Dear Mr. Herrera,

The U.S. Food and Drug Administration (FDA) inspected your firm located at Apartado Postal 306 Escazu, San Jose, Costa Rica on August 19-21, 2002, and found that you have serious deviations from the Hazard Analysis Critical Control Points (HACCP) regulations – Title 21 of the Code of Federal Regulations (CFR), Part 123. CFR Section 123.6(g), provides that a processor's failure to have and implement a HACCP plan that complies with this section or otherwise to operate according to the requirements of Part 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your Fresh Fish Raw, (scombroid species), Shrimp and Lobster are adulterated under the Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations include the following:

1. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." Your firm's HACCP plan for:

> Fresh Fish, Raw does not list the food safety hazard of *Clostridium botulinum* growth and toxin formation. Packaging conditions that reduce the amount of oxygen present in the package, such as vacuum packaging, increases the potential for formation of *Clostridium botulinum* toxin. Since your product is a vacuum packed raw fish, the target pathogen for control is *Clostridium botulinum.* The FDA Investigator reported that you did not identify *Clostridium botulinum* as a potential hazard in your vacuum packed raw fish because one hole is poked in each bag. This may not be sufficient to eliminate this hazard. You need to provide a study to show that this is sufficient to eliminate the

hazard.

Fresh Shrimp, Farm Raised, Raw and Frozen, does not list the food safety hazard of Aquacultured Drug. Your HACCP Plan identifies Aquaculture drugs used during the raising of shrimp species in aquaculture operations. You must assure that the drugs used on the fish you intend to import into the United States are approved for use in the U.S. and that the approved drugs are used in a manner recommended by the manufacturer.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels." Your firm's HACCP plan for fresh fish, raw (scombroid species) does not list the critical control point of Finished Product Storage for controlling the food safety hazard of histamine. Our investigator observed that finished products could be stored in excess of 12 hours. FDA would expect you to assure that the goods are adequately cooled during storage or assure safe product temperatures just prior to shipment.

3. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Your firm's HACCP plan for:

Fresh Fish, raw (scombroid species) does not list critical limits at the critical control point of Receiving to control the food safety hazard of histamine. If you receive fish directly from the fishing vessels, in addition to checking the internal temperature of the fish upon receipt, the U.S. Food and Drug Administration (USFDA) recommends one of two options for controlling the histamine hazard at receiving: (1) harvest vessel control and sensory examination of a representative sample of fish or (2) histamine testing and sensory examination of a representative sample of fish. Your plan lists that you require the presence of a letter of guarantee from the harvest vessels. FDA does not consider this an adequate method of control unless the guarantee contains all the elements of a harvest vessel record showing the harvesting and handling conditions of the fish during capture and storage. Chapter 7 of the FDA Fish and Fisheries Products Hazards and Controls Guidance: Third Edition June 2001 (The Guide), can provide specific information of what FDA considers necessary for handling records. Please be aware that FDA has also established safety criteria for sensory examinations and internal temperatures with regards to sample size.

Fresh Wild Shrimp, raw and frozen (with no sulfites) and fresh lobster, raw and frozen (with no sulfites) lists a critical limit for sulfites of "sulfiting agents used in concentration levels lower than 10 ppm" at the critical control point of Receiving that is not adequate to control the food safety hazard of sulfites. When sulfiting agents are added directly to a finished food, such as shrimp you process, they must be declared on the product's labeling regardless of the concentration of the sulfiting agent.

Please respond in writing within six (6) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation such as a corrected HACCP plan, copies of completed monitoring records showing your implementation of the changes (translated into English), or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in imports of your products being placed on "Detention Without Physical Examination."

This letter and the inspectional observations (Form FDA 483 issued to you at the close of the inspection) may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Brian S. Landesberg, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Import Branch, HFS-606, 5100 Paint Branch Parkway, College Park, Maryland 20740 USA. If you have questions regarding any issue in this letter, please contact Mr. Landesberg at (301) 436-1622.

Sincerely,

Judith A. Gushee
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
And Applied Nutrition